

REMARKS

This is in response to the Office Action dated April 20, 2005, in which claims 14, 18, 19, 29-33, and 34-38 were rejected under 35 U.S.C. § 102(b) as being anticipated by Swartz et al. (U.S. Pat. No. 5,993,593); and claims 14-19 and 23-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Swartz et al. With this Amendment, claims 16 and 27 have been canceled; claims 14 and 23 have been amended; and the specification has been amended to remove references to ultra-high molecular weight polyethylene (UHMW PE) in light of the amendment filed on February 1, 2005. Claims 14, 15, 17-19, 23-26, and 28-38 remain pending in the present application.

Claims 16 and 27 are canceled without prejudice. In light of the cancellations, the rejections to claims 16 and 27 should be withdrawn.

In the Office Action, claim 14 was rejected under 35 U.S.C. § 102(b) as being anticipated by Swartz et al. and under 35 U.S.C. § 103(a) as being unpatentable over Swartz et al. Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Swartz et al. These rejections will be addressed collectively.

Claims 14 and 23 have been amended to include a “pyrogen-free sterilized” bag comprised of a polymeric film comprising a polymer from a listed group that is suitable for heating to at least approximately 253° Celsius for at least approximately 30 minutes and/or wherein said bag has been heated to at least approximately 253° Celsius for at least approximately 30 minutes.

As set forth in the MPEP, a “claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (MPEP 2131). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success

must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (See MPEP 2142).

Swartz et al. do not disclose, teach or suggest a pyrogen-free (i.e., free of bacterial toxin) and sterilized bag. Accordingly, Swartz et al cannot anticipate the presently claimed subject matter under 35 USC § 102 or render it obvious under 35 USC § 103.

More specifically, Swartz et al. merely mention heating in the context of sealing the edges of heat-sealed bags. Applicants submit that heat sealing a bag is not the same as heat sterilizing the entire lining of a polymeric bag to result in a pyrogen-free sterilized product. Swartz et al. do not disclose, teach or suggest heating a bag to at least approximately 253° Celsius for at least approximately 30 minutes to ensure that the bag is pyrogen-free and sterilized. By contrast, amended claims 14 and 23 require that the bag is suitable for heating to at least approximately 253° Celsius for at least approximately 30 minutes to ensure that the bag is pyrogen-free and sterilized. As disclosed in the specification, "...current requirements by the FDA for the sterilization and removal of pyrogen from containers, bags, etc. includes that the interior lining being heated to at least 253° Celsius." (Para. [0040], lines 22-24).

In the Office Action, the Examiner asserts that Swartz et al "teaches heat-sealed bags (col. 3, line 31) made using PEEK polymers that are heat sealed at temperatures of 205° to 580° C (claims 31 and 33 of the patent)". The Office Action relies only on a brief mention of polyetheretherketone (PEEK, one of the listed polymers in claims 14 and 23) as a basis for rejection. Swartz et al. do not disclose, teach or suggest using PEEK to form heatable pyrogen-free bags. Contrary to the assertions in the Office Action, Swartz merely describes the use of PEEK as a sealant and the application of elevated temperatures for heat sealing (Column 8, lines 34-43 and claim 33). Thus, Swartz et al. only teach using PEEK as the sealant of the heat-sealed bags, not as the polymer forming the actual bag itself. "Suitable materials for use in forming this first type of seal are LCP, PEEK...." By contrast, claims 14 and 23 of the present invention require that the bag be comprised of a polymeric film comprising a polymer "... (PEEK)...."

Furthermore, Swartz et al. teach against using PEEK for forming heat-sealed bags. As disclosed in Swartz et al., "There is a widespread interest in LCP films because, unlike films made from other high-performance polymers, such as polyetheretherketone (PEEK)...which are based on exotic and inherently expensive chemistries, LCP films are based on polyester chemistry...." (Column 1, lines 26-32). By contrast, the heat-sealed bag of the present invention uses PEEK as one of the preferred polymers for forming the polymeric film-based bag. Swartz et al. do not disclose, teach or suggest a bag comprised of a polymeric film comprising a polymer PEEK. Claims 14 and 23 require that the bag be comprised of a polymeric film comprising a polymer selected from a listed group, including PEEK.

Additionally, amended claims 14 and 23 require that the bag be suitable for heating to at least approximately 253° Celsius for at least approximately 30 minutes. Swartz et al. do not disclose, teach or suggest heating the heat-sealed bag for at least 30 minutes. Rather, Swartz et al. teach heating above a temperature of 253° Celsius only for very short periods of time. As disclosed in the specification, "...high temperature film are sealed by bringing the temperature of the sealing element above about 425° C...quickly (in about 0.05 second) and rapidly returning the heat sealed region to room temperature (in about 3 seconds or less)." (Column 8, lines 52-56), and "This is accomplished by commingling the sealed edges of the total laminate, including the thin LCP layers using a median temperature of 425° C...but with very short impulse (less than 0.5 second) and immediately cooling the commingled materials at the seal line to room temperature in less than 3 seconds." (Column 9, lines 12-17). By contrast, amended claims 14 and 23 require that the bag be suitable for heating to at least approximately 253° Celsius for at least approximately 30 minutes.

Furthermore, with respect to any suggestion that claim limitations relating to film thickness, heating times, content and other claim limitations are "deemed matters of engineering/design choice, depending upon the particular use to which the films and bags of Swartz are to be put", Applicants submit that there is no evidence of record demonstrating that it would have been obvious to modify Swartz to result in the claimed invention. The mere fact a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the modification (MPEP 2143.01). A statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the

claimed invention was made' " because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. (MPEP 2143.01)

Also, with respect to the suggestion that certain claim limitations are "intended use" limitations, Applicant's direct the Examiner's attention to MPEP 2173.05(g) which states:

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. Whether or not the functional limitation complies with **35 U.S.C. § 112**, second paragraph, is a different issue from whether the limitation is properly supported under **35 U.S.C. § 112**, first paragraph, or is distinguished over the prior art. A few examples are set forth below to illustrate situations where the issue of whether a functional limitation complies with **35 U.S.C. § 112**, second paragraph, was considered.

It was held that the limitation used to define a radical on a chemical compound as "incapable of forming a dye with said oxidizing developing agent" although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought. *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971).

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

Applicants submit that each limitation of every claim requires consideration in the Office Action.

Moreover, with respect to any allegation that Swartz inherently describes the present invention:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization

of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

[MPEP 2112]

Thus, because Swartz et al. does not disclose, teach or suggest a pyrogen-free sterilized bag of any of the listed polymers that is suitable for heating to at least approximately 253° Celsius for at least approximately 30 minutes and/or wherein said bag has been heated to at least approximately 253° Celsius for at least approximately 30 minutes, the rejections to claims 14 and 23 as being unpatentable over Swartz et al. should be withdrawn and claims 14 and 23 allowed.

In that claim 14 is in condition for allowance, the rejections of claims 15, and 17-19, which depend therefrom, should be withdrawn as well and claims 15, and 17-19 allowed.

In that claim 23 is in condition for allowance, the rejections of claims 23-26 and 28-38, which depends therefrom, should be withdrawn as well and claims 23-26 and 28-38 allowed.

The specification has been amended to remove references to ultra-high molecular weight polyethylene (UHMW PE) in light of the amendment filed on February 1, 2005.

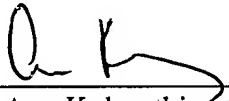
CONCLUSION

In view of the foregoing, all pending claims 14, 15, 17-19, 23-26, and 28-38 are in condition for allowance. Reconsideration and allowance of all pending claims are respectfully requested.

Respectfully submitted,

KINNEY & LANGE, P.A.

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By 
Ann Kulprathipanja, Reg. No. 50,608
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

DRF/PGK/AK:hlw